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PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#7/56

Group Art Unit 3732	:	PATENT APPLICATION
Examiner David A. Bonderer	:	
In re application of	:	PATELLA REPLACEMENT APPARATUS
ROBERT S. SUPINSKI	:	
Serial No. 10/007,812	:	
Filed November 8, 2001	:	

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TECHNOLOGY CENTER R3700

DECLARATION OF DR. ROBERT SUPINSKI UNDER 37 C.F.R. § 1.131

I, Robert Supinski, am the inventor of the patella replacement apparatus that is disclosed and claimed in the above-titled application. I am an orthopedic surgeon and have been performing orthopedic surgery since 1985.

In 1989 I conceived of a patella replacement device that could be used in repairing or replacing the destroyed natural patella of a patient. This device has two hemispherical parts and an annular ring, all fabricated from a biocompatible material. At that time I conceived that the ring and one hemispherical member would be a biocompatible metal such as titanium and the other hemispherical member would be plastic, particularly polyethylene. Posts provided on one member would fit into holes in the other member.

I made my first drawing of this patella replacement device in the fall of 1989. I am unable to locate that first drawing and believe it to have been destroyed.

On or about February 8, 1990, I disclosed my idea to Gregory Gray, a biomechanical engineer, in confidence. I asked Mr. Gray to assist me in developing a prototype of this device.

Mr. Gray sent me a letter dated February 14, 1990, which makes reference to that discussion. That letter is attached as Exhibit I.

During February and March of 1990, I had several discussions with Mr. Gray about creating a prototype of the patella replacement device. On March 15, 1990, I wrote a recap of one discussion that we had on March 7, 1990, about the prototype. A copy of those notes is attached as Exhibit II.

On or about March 7, 1990, I conceived that a better patella replacement device could be made by coating one or both hemispherical components with hydroxyapatite to provide a porous structure into which bone and soft tissue can grow. This concept is shown in the drawing contained in my notes marked as Exhibit II. Therefore, I worked with people at Dow Custom Products to have a drawing and prototype of the device made. At my direction a formal drawing was prepared by Mr. Gray of Dow Custom Products from my hand sketch and other information that I provided. The drawing was made on or about March 14, 1990. A copy of the March 14, 1990, drawing and cover letter from Mr. Gray is attached as Exhibit III.

During March, 1990, Mr. Gray was also working on making a prototype of my patella replacement device. I understand that this prototype was completed on March 15, 1990. This was the first prototype of my patella replacement device. The drawing in Exhibit III is the earliest drawing of my invention that I have been able to locate.

On August 21, 1990, I implanted the prototype device in a patient. Although I then believed that this device would work, it was necessary to implant the device in a patient and chart his progress before the product would be accepted by the medical community. Attached as Exhibit IV is a report of the surgery during which my patella replacement device was implanted. The patient's name has been redacted from the report. Following surgery I examined the patient

at regular intervals. The patient was able to resume normal activities indicating that the patella replacement was successful.

In May of 1992 I had a patella replacement device with a hydroxyapatite coating made for another one of my patients. I implanted that device in the patient on May 12, 1992, and examined the patent at intervals after surgery. The patient was able to resume normal activities and be pain free. A second operative procedure was performed at a later date and the device was inspected and found to be functioning well. Attached as Exhibit V and Exhibit VI are the operative reports dated May 12, 1992, and November 12, 1998. The patient's name has been redacted from the reports. Subsequently, I implanted other prototypes in other patients. All were able to regain improved or nearly complete function of the knee joint and suffered no discomfort after the healing.

On or about November 12, 1998, I realized that the annular ring was not necessary and indeed could cut through the prosthesis or surrounding soft tissue. Therefore, I worked with the people in the Custom Engineering Department at Biomet to have a drawing and prototype made. Attached as Exhibits VII and VIII is a hand drawing that I made of this device on January 26, 2001, and a subsequent formal drawing made by Biomet on February 9, 2001.

In July, 2001, I spoke to my patent attorney about obtaining patent protection for the various embodiments of my patella replacement device. This resulted in the preparation and filing of the present application.

I declare that the foregoing is true and correct, that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such

willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: January 2, 2004

Dr. Robert Supinski